K062125

1/2

OCT 19 2006

510(k) SUMMARY

Sutura, Inc.'s SuperStitch® 5F, 12F & EL

OCT 19 2006

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Sutura, Inc.
17080 Newhope St.
Fountain Valley, California 92708

Phone: (714) 437-9801
Facsimile: (714) 437-9806

Contact Person: Anthony Nobles
Date Prepared: July 19, 2006

Alternate Contact:

Gerard J. Prud'homme
Hogan & Hartson L.L.P.
555 Thirteenth St., NW
Washington D.C., 20004
Phone: (202) 637-5600

Name of Device and Name/Address of Sponsor

SuperStitch 5F, 12F & EL

Sutura, Inc.
17080 Newhope St.
Fountain Valley, California 92708

Common or Usual Name

SuperStitch Guidewire Vascular Suture Delivery Device

K062125
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Classification Name

Suture, Nonabsorbable, Synthetic, Polypropolene

Predicate Devices

Sutura's SuperStitchVascular Suturing Device

Intended Use/Indications for Use

The SuperStitch 5F, 12F & EL sizes are indicated for use in performing vascular stitching in general surgery, including endoscopic procedures. The SuperStitch 5F, 12F & EL are not intended for blind vascular closure.

Technological Characteristics

The SuperStitch 5F, 12F & EL versions are hand-held and manually operated suturing devices designed to allow a physician to place a suture to a remote site either directly, through a cannula/introducer, or through a laparascopic access device. The device contains the following components and accessories: a suture delivery device, monofilament polypropylene suture, a pre-loaded guidewire, a KnotPusher accessory for advancing the knot to the wound site, and a KwiKnot accessory.

Substantial Equivalence

The SuperStitch 5F, 12F & EL has the same intended use and indications for use, principles of operation, and fundamental technological characteristics as the currently marketed SuperStitch, except that the SuperStitch 5F, 12F & EL provide the option of diameter or lengths for use by the physician. This minor modification to the SuperStitch does not raise any new questions of safety or effectiveness. Thus, the SuperStitch 5F, 12F & EL are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2006

Sutura, Inc.
% Hogan & Hartson, L.L.P.
Mr. Gerard J. Prud'homme
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K062125
Trade/Device Name: SuperStitch® 5F Vascular Suture Delivery Device
SuperStitch® 12F Vascular Suture Deliver Device
SuperStitch® Extended Length Vascular Suture Deliver Device
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: September 21, 2006
Received: September 21, 2006

Dear Mr. Prud'homme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

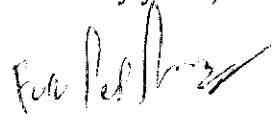
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062125

Indications for Use Statement

510(k) Number (if known):_____

Device Name: SuperStitch® 5F Vascular Suture Delivery Device
SuperStitch® 12F Vascular Suture Delivery Device
SuperStitch® Extended Length Vascular Suture Delivery Device

Indications for Use:

The SuperStitch 5F, 12F & EL is indicated for use in performing vascular stitching in general surgery, including endoscopic procedures. The SuperStitch 5F, 12F & EL is not intended for blind vascular closure.

Prescription Use __X___ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062125